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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,064	10/23/2003	David F. Davenport	03880-P0001B	7267
24126 7590 04/11/2007 ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 06905-5619			EXAMINER FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1655	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/11/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/692,064

Applicant(s)

DAVENPORT ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-21 and 46-69 is/are pending in the application.
- 4a) Of the above claim(s) 64-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-21 and 46-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on January 10, 2007 with the addition of newly submitted Claims 63-69.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Election/Restrictions

Newly submitted claims 64-69 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally presented claims were directed to a composition comprising a glucosamine component base and at least one nutrient component, wherein the glucosamine component is in an effective amount such that when administered to a mammal, the nutraceutical composition is effective to improve fertility, whereas the invention of Claims 64-68 are directed to a nutraceutical composition comprising a glucosamine component and at least one nutrient component, wherein the glucosamine component and the at least one nutrient component are in an effective proportion and an effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility; and, whereas the invention of Claim 69 is directed to a nutraceutical composition comprising a glucosamine component and at least two nutrient components selected from a group consisting of an oil cake component, an acid component, a mineral component, a vitamin component, and a functional food

component; wherein the glucosamine component and the at least two nutrient components are in effective proportion and effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 64-69 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 18-21 and 46-63 are under examination.

Claim Rejections - 35 USC § 112

Claims 50-63, as amended, remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 50 fails to further limit the subject matter of Claim 18 from which the claim depends because the instantly claimed subject matter of Claim 18 already comprises a nutrient component.

The metes and bounds of Claim 53 are rendered uncertain by the phrase "wherein said acid component is ascorbic acid, least one derivative thereof, lipoic acid, or dihydrolipoic acid" because it is unclear as to whether the acid component must comprise both ascorbic acid and at least one derivative thereof or either of the other, since the recitation of the claim is not set forth in terms of the alternative, with regard to the claim limitation of lipoic acid or dihydrophilic lipoic acid which follow the recitation of the aforementioned phrase. The lack of clarity renders the claim ambiguous.

Claim 58 recites the limitation "the selected nutrient component" in line 1 to line 2. There is a lack of sufficient antecedent basis for this limitation in the claim.

Claims 58, 60 and 61 remain rejected because the claims recite the abbreviation "pbw". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indication in parentheses. The abbreviations can be used thereafter. Applicant may overcome the rejection by replacing the abbreviation with parts by weight (pbw).

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

Claims 18-21 and 46-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Rovati (A*) and Schleck et al. (B*). Claim 50 newly applied, as necessitated by amendment. Applicant's arguments have been fully considered but found unpersuasive. The rejection remains the same for the reason set forth in the previous Office action and for the reason set forth below.

Applicant claims a nutraceutical composition comprising a glucosamine component base and at least one nutrient component, wherein the glucosamine component is in an effective amount such that when administered to a mammal the nutraceutical composition is effective to improve fertility.

Applicant argues that Rovati fails to anticipate the instantly claimed invention because the teachings of Rovati are directed to process for generating pure glucosamine sulphate and glucosamine hydroiodide. Applicant further argues that Rovati does not disclose a nutraceutical composition wherein the glucosamine is in an effective amount to improve fertility and that Rovati does not disclose that the glucosamine forms the base of the formulation with at least one nutrient component. Applicant's arguments have been fully considered but not found persuasive because Rovati teaches a composition comprising glucosamine hydrochloride and water (read herein as a liquid dosage form), in Column 4, lines 1-3. As water is a nutrient, the composition taught by Rovati teaches the instantly claimed invention.

Applicant argues that Schleck fails to anticipate the instantly claimed invention because Schleck only teaches a composition that contains glucosamine sulfate metal

chloride. Applicant's arguments have been fully considered but not found persuasive because Schleck teaches a composition comprising glucosamine hydrochloride and water (read herein as a liquid dosage form), in Column 3, lines 45-48. As water is a nutrient, the composition taught by Schleck teaches the instantly claimed invention.

It is noted that the references do not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "wherein the glucosamine component is in an effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference; thus, the intended use is not limiting.

Applicant argues that "an effective amount" places a functional limitation of the claimed composition and is determined in light of Applicant's application. Applicant

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further argues, "In order to anticipate, a cited reference must disclose a range that is sufficiently specific." Applicant cites case law. Applicant's arguments have been fully considered but are neither persuasive nor commensurate in scope to the limitations of the instantly claimed invention. While the Examiner has interpreted the claims in light of the present specification, Applicant is reminded that limitations set forth in the specification cannot be read into the claims. Moreover, the claims, as presently drafted, fail to provide any limitations for a specific range of the ingredients comprising the instantly claimed composition.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The references anticipate the claimed subject matter.

Claims 18-21, 46-51, 57-59, 61 and 62, as amended, remain rejected under 35 U.S.C. 102(e) as being anticipated by Watson et al. (C*). Applicant's arguments have been fully considered but found unpersuasive. The rejection remains the same for the reason set forth in the previous Office action and for the reason set forth below.

Applicant's main argument is directed to the idea that Watson fails to teach the instantly claimed invention because the formulation taught by Watson incorporates N-acetyl glucosamine as a minority component. Applicant further argues that the Watson does not disclose that the N-acetyl glucosamine is in an effective amount to improve

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fertility. Finally, Applicant argues that Watson does disclose that the N-acetyl glucosamine forms the base of the formulation with at least one nutrient component or that the N-acetyl glucosamine and any other component are in effective proportion and effective to improve fertility. Applicant's arguments have been fully considered but found unpersuasive. For instance, Watson teaches a composition comprising from about 5 to about 20 weight percent of N-acetylglucosamine; a synbiotic mixture of 20 to about 60 weight percent of a probiotic (functional food component;) and 10 to about 50 weight percent of fructooligosaccharides (functional food component, probiotic for bifidobacteria, thereby a prebiotic); and from about 15 to about 50 weight percent of glutamine (a nutrient, functional food component). As the composition taught by Watson, may comprise at least equal portions of N-acetyl glucosamine in relation to the other ingredients comprising the referenced composition, the N-acetyl glucosamine incorporated into the making of the Watson' formulation may form the base of the referenced composition. See Column 1, line 60 bridging Column 2, line 60. The composition taught by Watson can be mixed together and formulated into tablets or capsules; and may further contain filler. See Column 2, lines 61-67.

It is noted that the reference does not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "wherein the glucosamine component is in an

effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference; thus, the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18-21, 46-51, 53, 58, 61 and 62, as amended, remain rejected under 35 U.S.C. 102(e) as being anticipated by Menard (D*). The rejection remains the same for the reason set forth in the previous Office action and for the reason set forth below.

Applicant argues that Menard fails to anticipate the instantly claimed invention because Menard discloses that the glucosamine is incorporated with linoleic acid and ascorbic acid over a broad range. Applicant also argues that the preferred embodiment

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indicates that the glucosamine is in equal contribution to the composition as linoleic acid. Applicant further argues that Menard does not disclose that the glucosamine comprising the referenced composition is in an effective amount to improve fertility or effective proportion as a base component with at least one nutrient component to improve fertility. Applicant's arguments have been found persuasive because Menard teaches a nutraceutical composition comprising glucosamine sulfate, ascorbic acid (a nutrient acid component) and linoleic acid, wherein the daily dose for delivery to a mammal comprises 1500 mg to about 2500 mg of the glucosamine component (glucosamine sulfate). See Column 5, lines 5-65. While Applicant may continue to argue that the Menard' composition does not incorporate glucosamine as a base component, given that the preferred embodiment teaches a composition comprising at least equal portions of glucosamine and linolenic acid, the composition taught by Menard comprises glucosamine as at least one base component. Moreover, the composition taught by Menard comprises the same daily dose amount of glucosamine as instantly claimed by Applicant as in effective amount to improve fertility (as set forth in the limitations of Claim 48). Therefore, the claim-designated functional effect of the glucosamine component comprising the Menard' composition is deemed to inherently improve fertility, when administered to a mammal, absent evidence to the contrary.

It is also noted that the reference does not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to

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instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "wherein the glucosamine component is in an effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference; thus, the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18, 21, 46-51, 53-56, 61 and 62, as amended, remain rejected under 35 U.S.C. 102(e) as being anticipated by D'Abramo (E*). Applicant's arguments have been fully considered but found unpersuasive. The rejection remains the same for the reason set forth in the previous Office action and for the reason set forth below.

Please note that the omission of Claims 50, 51 and 54-56 in the previous Office action was an obvious typographical error, given that the Examiner set forth the limitations of the instantly claimed invention repeated herein for convenience.

Applicant's claimed invention of Claims 18, 21, 46-49, 58, 61 and 62 was set forth above. Applicant further claims the composition of claim 51, wherein said mineral component further comprises at least one mineral selected from the group consisting of zinc, boron, chromium, manganese, and combinations thereof; wherein said mineral acid component is further characterized as an amino acid chelate; wherein said vitamin further comprises at least one vitamin selected from the group consisting of biotin, thiamine HCL, folic acid, and combinations thereof.

Applicant's main argument is directed to the idea that D'Abramo does not teach a nutraceutical composition because D'Abramo discloses a diet product for the culture of larval fish and crustaceans comprising glucosamine as a tiny fraction of the overall composition. Applicant also argues that the D'Abramo does not disclose that the glucosamine is in effective amount to fertility or forms the base of the referenced composition with at least one nutrient component or any other component in effective proportion to improve fertility. Applicant's arguments have been fully considered. However, Applicant's arguments are not persuasive because D'Abramo teaches a composition comprising glucosamine; ascorbylpalmitate; a Vitamin premix including thiamine, folic acid, biotin and ascorbic acid (; a mineral premix including zinc and an amino acid chelate, e.g., magnesium oxide. Furthermore, while D'Abramo does not expressly teach the referenced composition as a nutraceutical composition, there is

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nothing contained therein the composition taught by D'Abramo to preclude the use of the composition as a nutraceutical composition.

It is also noted that the reference does not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "wherein the glucosamine component is in an effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference; thus, the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18, 21, 46-53, 58 and 60-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Meisner (F*). Applicant's arguments have been fully considered but found unpersuasive. The rejection remains the same for the reason set forth in the previous Office action and for the reason set forth below.

Applicant argues that the composition taught by Meisner is ascorbic-based composition and that the composition can include glucosamine at 5-20% w/v). Applicant further argues that Meisner does not disclose a composition comprising a nutraceutical composition. Applicant further argues that Meisner does not teach disclose that the glucosamine is in an effective amount to improve fertility or that the glucosamine and any other component are in effective proportion and effective amount to improve fertility. Applicant's arguments have been fully considered. However, Applicant's arguments are not persuasive because Meisner does indeed teach a composition comprising glucosamine and a nutrient. For instance, Meisner teaches a composition, in solid dosage form or liquid dosage form, comprising at least about 10% of an ascorbic acid or an ascorbic acid comprising monodehydroascorbic acid, zinc, soy flour, and filler.¹ See patent claims 1, 3-6, 9, 15 and 16. As the patent claims provide for a composition comprising at least 10 of an ascorbic acid and 20% glucosamine, a composition comprising a glucosamine component and a nutrient are taught by Meisner.

It is also noted that the reference does not teach that the composition can be used in the manners instantly claimed, however, the intended use of the claimed

composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "wherein the glucosamine component is in an effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference; thus, the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 18, 20, 21, 46-51 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Abe et al. (U). Applicant's arguments have been fully considered but

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found unpersuasive. The rejection remains the same for the reason set forth in the previous Office action and for the reason set forth below.

Applicant argues that the composition taught by Abe is not a nutraceutical composition. Applicant further argues that Abe does not disclose that the glucosamine is in an effective amount to improve fertility. Finally, Applicant argues that Abe fails to disclose that the glucosamine forms the base of a formulation with at least one nutrient component or that the glucosamine and any other component are in effective proportion and effective amount to improve fertility. Applicant's arguments have been thoroughly considered but found unpersuasive because Abe teaches a composition comprising copper N-succinyl glucosamate (a glucosamine component and a mineral/functional food component, that is copper), in aqueous solution (read herein as a nutrient component, given that water is a nutrient) liquid dosage form, which was administered to mammals for the induction of ovulation in dose amounts of 4 mg/kg/body weight to 10 mg/kg/body weight. While Abe does not expressly teach the referenced composition as a nutraceutical composition, there is nothing in the composition taught by Abe to preclude the use of the composition as a nutraceutical composition.

It is also noted that the reference does not teach that the composition can be used in each of the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. With particular regard to instant Claims 18 wherein Applicant directs the instantly claimed subject matter to a composition comprising a glucosamine component "wherein the glucosamine

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component is in an effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility"; and, to instant Claims 48 and 49 wherein Applicant directs the instantly claimed subject matter to a composition, wherein the composition is provided to the mammal as a daily dose comprising claim designated amounts of a glucosamine component, the Office notes that claims drafted in terms of post use of a composition do not impart a patentable distinction between a claimed composition and its method of use thereof. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference; thus, the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
March 31, 2007